

**Notice of Allowability**

Application No.

09/189,415

Examiner

S. Devi, Ph.D.

Applicant(s)

FINLAY ET AL.

Art Unit

1645

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 07/24/06.
2. ☒ The allowed claim(s) ~~is/are~~ 7, 52, 62, 63 and 65-68, now renumbered as claims 1, 2, 3, 4 and 5-8 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS ( as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |   |   |
|---|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)           |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input type="checkbox"/> Examiner's Statement of Reasons for Allowance             |
|   | 9. <input type="checkbox"/> Other _____   |

## ATTACHMENT TO NOTICE OF ALLOWABILITY REQUEST FOR CONTINUED EXAMINATION

1) A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicants' submission filed on 02/10/06 has been entered.

### Applicants' Amendments

2) Acknowledgment is made of Applicants' amendments filed 02/10/06, 05/18/06 and 07/24/06 in response to the final Office Action mailed 11/08/05. The amendment filed 07/24/06 is compliant. With this, Applicants have amended the specification and the claims.

### Examiner's Amendment

3) An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to Applicants, an amendment may be filed as provided by 37 C.F.R. 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee. The authorization to prepare this Examiner's amendment was provided by Mr. Andrew Serafini in a telephonic interview on 17 August 2006.

This application has been amended as indicated below:

- (a) Claims 64 and 75 have been canceled.
- (b) Claims 62, 63, 65 and 66 have been amended as indicated below:
  - Claim 62 (Currently amended). [[A]] An isolated Tir (translocated intimin receptor) polypeptide fragment comprising the amino acid sequence set forth in SEQ ID NO: 7.--
  - Claim 63 (Currently amended). An isolated Tir polypeptide fragment that consists of 8 consecutive amino acids of the amino acid sequence of SEQ ID NO: 11.--
  - Claim 65 (Currently amended). A fusion protein comprising an isolated Tir polypeptide that comprises the amino acid sequence of SEQ ID NO: 11, wherein the Tir polypeptide is fused to a non-Tir protein sequence.--
  - Claim 68 (Currently amended). The fusion protein of claim 65 wherein the non-Tir protein

~~sequence~~ is a marker polypeptide selected from the group consisting of an enzyme, a fluorescence protein, and a luminescent protein.--

(c) The instant specification has been amended as indicated below:

Lines 27 and 28 of page 7 of the specification are replaced with the following:

--FIG. 9A-B shows the sequence similarity between Tir polypeptides from EPEC (SEQ ID NO: 10), EHEC (SEQ ID NO: 11) and RDEC-1: (SEQ ID NO: 12). SEQ ID NO: 12 is the deduced amino acid sequence of SEQ ID NO: 5.--

### **Status of Claims**

- 4) Claims 6, 23 and 60 have been canceled via the amendment filed 05/18/06.  
Claims 52, 63-65 and 74 have been amended via the amendment filed 05/18/06.  
New claim 75 has been added via the amendment filed 05/18/06.  
Claims 64 and 75 have been canceled via this Examiner's amendment.  
Claims 62, 63, 65 and 68 have been amended via this Examiner's amendment.  
Claims 7, 52, 62, 63 and 65-68 are pending and are under examination.

### **Objection(s) Withdrawn**

- 5) The objection to the specification made in paragraph 19(i)(a) of the Office Action mailed 11/08/05 is withdrawn in light of Applicants' amendments to the specification and Applicants' arguments.
- 6) The objection to the specification made in paragraph 19(i)(b) of the Office Action mailed 11/08/05 is withdrawn in light of Applicants' amendment to the specification.
- 7) The objection to the specification made in paragraph 19(i)(c) of the Office Action mailed 11/08/05 is withdrawn in light of Applicants' amendment to the specification and Applicants' arguments.
- 8) The objection to the specification made in paragraph 19(ii) of the Office Action mailed 11/08/05 is withdrawn in light of Applicants' amendments to the specification and sequence listing.
- 9) The objection to the specification made in paragraph 19(iii) of the Office Action mailed 11/08/05 is withdrawn in light of Applicants' amendments to the specification

### **Rejection(s) Moot**

**10)** The rejection of claim 69 and those dependent therefrom made in paragraph 23 of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claim.

**11)** The rejection of claims 70-72 made in paragraph 24 of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.

**12)** The rejection of claims 69-72 made in paragraph 25 of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is moot in light of Applicants' cancellation of the claims.

**13)** The rejection of claim 69 made in paragraph 26(a) of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

**14)** The rejection of claim 69 made in paragraph 26(b) of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claim.

**15)** The rejection of claims 70-72 made in paragraph 26(c) of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, second paragraph, as being indefinite, is moot in light of Applicants' cancellation of the claims.

### **Rejection(s) Withdrawn**

**16)** The rejection of claim 65 and those dependent therefrom made in paragraph 21 of the Office Action mailed 11/08/05 under 35 U.S.C. § 101 as being directed to non-statutory subject matter, is withdrawn in light of Applicants' amendment to the claim.

**17)** The rejection of claim 52 made in paragraph 22 of the Office Action mailed 11/08/05 under 35 U.S.C. § 112, first paragraph, as containing new subject matter, is withdrawn in light of Applicants' amendment to the claim.

**18)** The rejection of claim 63 made in paragraph 27 of the Office Action mailed 11/08/05 under 35 U.S.C. § 102(b) as being anticipated by Webster *et al.* (*Mechanisms of Development* 38: 25-32, 1992), is withdrawn in light of Applicants' amendment to the claim.

### Remarks

**19)** Claims 7, 52, 62, 63 and 65-68, now renumbered as claims 1, 2, 3, 4 and 5-8 respectively, are allowed.

The new limitation 'translocated intimin receptor' added to claim 62 above is supported at line 14 on page 3 of the instant specification. The sequence ID NO: 5 is a part of the originally filed sequence listing.


**20)** Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

**21)** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**22)** Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (571) 272-0864.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

  
S. DEVI, PH.D.  
PRIMARY EXAMINER

August, 2006